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| EXAMINER | |
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| ELLIS, SUEZU Y | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/507,094 | MASPERO ET AL. | |
| | Examiner | Art Unit | |
| | Suezu Ellis | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *44-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**FINAL REJECTION**

***Response to Arguments***

Applicant's arguments with respect to claims 14-43 have been considered but are moot in view of the new ground(s) of rejection.

Examiner notes that on the first page of applicant's remarks, applicant states that claim 14 was amended to recite "a major portion of the surface area", in accordance with the examiner's suggestion. However, this is incorrect. It appears the applicant misrepresented the examiner's intention. Examiner only inquired about the interpretation of the limitation "a major portion of said granules coated with..." in the 112 rejection mailed on February 26, 2008, and did not provide a suggestion for amending the claim. Examiner did not provide a suggestion, but merely pointed out different ways of interpreting that limitation.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 14, the specification specifically states that granules are coated with a polymer (pg. 6, lines 1-3) and that there can be coated and uncoated granules (pg. 11, paragraph beginning with “Biocompatible and biodegradable implants…”). However there is no discussion of partially coating the granules, as implied by the new claim language “a majority of the surface area of said granules are coated with...", only that one can have coated and uncoated granules. Therefore, the new claim limitation “a majority of the surface area of said granules are coated with...", is considered new matter.

With respect to claim 26, the specification does not appear to have support for the combination of both hollow granules with at least one opening in the granule wall and porous granules, wherein the opening in the granule wall is larger than the average diameter of the micropores in the porous granules, therefore, fails to comply with the written description requirement.

Claims 15-43 fail to comply with the written description requirement due to their dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "a major portion of the surface area" in claim 14 is a relative term which renders the claim indefinite. The term "a major portion of the surface area" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is considered “a major portion”. Please clarify.

Claim 26 recites the limitation "the micropores" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is unclear what micropores applicant is referring to since neither claim 14 nor claim 23 recite micropores. Further, it is unclear from the claim language if the granules are hollow instead of porous, or if the implant has a combination of both porous granules and hollow granules with at least one opening. Please clarify.

Claim 29 recites the limitation "the macropores" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear what macropores applicant is referring to since claims 14, 23 and 26 fail to recite the any limitation referring to macropores.

With respect to claim 35, claim language recites the term "a homogeneous thickness". It is unclear what a homogeneous thickness is. Does applicant mean a uniform thickness? Please clarify.

Claims not specifically addressed are indefinite due to their dependency.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-20, 23, 32, 33 and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 4,645,503) in view of Ricci et al. (US 2002/0016636).

With respect to claims 14-17 and 23, Lin et al. discloses a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage (polymer binder), and the granules made of hydroxyapatite and a major portion of the surface area of the granules are coated with polylactic acid. Lin et al. also discloses the granules can have a particle size of 650 μm, which falls within the claimed ranges of 350-2000 μm and 500-1000 μm (col. 3, lines 26-30, 35-39; col. 5, lines 66-67).

Lin et al. discloses the polymer coating having a volume fraction of about 5-20% of the total solid volume of the material (col. 5, lines 62-65), however fails to expressly disclose the polymer coating having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of the implant. Ricci et al. discloses a bioresorbable implant comprising calcium sulfate particles coated with resorbable polymers, wherein the resorbable polymer is made of

polylactides or polyglycolides [0025]. Ricci et al. further discloses the polymer coating having a thickness of about 2 μm to about 50 μm and being a range of 0.1% to 50% by weight in order to control the resorption rate of the implant composition [0022], [0026]. It would have been an obvious design modification to one of ordinary to modify the thickness and/or the content of the polymer coating of Lin et al. in order to give easy formability and provide sufficient particle cohesion and shape retention during the period of tissue ingrowth while attaining the desired resorption rate (col. 2, lines 61-64; col. 4, lines 41-46). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 18 and 19, the modified Lin et al. discloses the granules are spherical (col. 5, line 59).

With respect to claim 20, the modified Lin et al. fails to expressly disclose the thickness of the polymer being in a range of 5 μm to about 20 μm. Ricci et al. discloses it is known in the art to coat a granule with a polymer, wherein the polymer coating has a thickness of about 2 μm to about 50 μm, which overlaps the claimed range [0022]. It would have been an obvious design modification to one of ordinary to modify the thickness of polymer in order to attain the desired resorption rate of the implant composition, as taught by Ricci et al. [0022]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 32 and 33, the modified Lin et al. discloses the implant is made of two or more kinds of granules, wherein the two or more kinds of granules are made of different biocompatible materials and implant is shaped in a manner to accommodate the granules (col. 3, lines 27-30; col. 6, lines 2-11; col. 7, lines 1-45).

With respect to claims 38-43, the recitations of “the granules are fused together in a mole in a pressurized $CO_2$ atmosphere under a pressure in a range of about 20 bar to about 200 bar, for at least about 3 seconds” and “the granules are fused together by subjecting them within a mold to a heat treatment at a temperature in a range of about 70° C to about 220° C for at least about 10 seconds” are believed to be process limitations that do not impart any recognizable distinguishing characteristic to the final product.

"Process limitations cannot impart patentability to product claim where product is not patentably distinguished over prior art." In re Dike, 157 USPQ 581 (CCPA 1968). See also MPEP 2113.

It is well-settled that the "[p]resence of process limitations in product claims, which product does not otherwise patentably distinguish over prior art, cannot impart patentability to that product." In re Stephens, 345 F.2d 1020 (CCPA 1965), 145 USPQ 565, citing Dilnot. In any event, the modified Lin et al. discloses the granules fused together in a mold. Thus, the modified Lin et al. expressly discloses every positively recited structural limitation, and thus meets the limitations recited in the claims, and the product-by-process limitations have not been given significant patentable weight.

Claims 21, 22, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. in view of Ricci et al. and further in view of Bauer et al. (US 5,338,772).

With respect to claims 21 and 22, the modified Lin et al. addresses all the limitations of claim 14, and further discloses the polymer-linkage is carried out such that after fusing the granules together, the implant material is porous (contains void spaces) (col. 5, lines 56-58). However, Lin et al. fails to expressly disclose an open-pore structure with macropores having an average diameter in the range of about 100-500 μm, or about 200-300 μm. Bauer et al. teaches a bone implant having macropores with sizes in the range of 0.01 – 1 mm (col. 4, lines 32-36; col. 5, lines 26-28), which overlaps with the claimed range. It would have been an obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only. *In re Aller*, 105 USPQ 233.

With respect to claim 24, the modified Lin et al. addresses all the limitations of claims 14 and 23, however fails to expressly disclose the granules are porous. Bauer et al. teaches it is known in the art to utilize porous biocompatible and biodegradable granules in bone filling material (col. 4, lines 27-30; 37-49). It would have been obvious to one of ordinary skill in the art to modify the granules of Lin et al. to be porous in order to optimize bone growth. Further, it has been held to be within the general skill of a

worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claims 25 and 28, Lin et al. fails to expressly disclose the granules having micropores having an average diameter in the range of 0-10 μm and macropores having an average diameter in the range of about 100-500 μm. Bauer et al. teaches a bone implant having both macropores and micropores, wherein the size of the macropore is in the range of 0.01 – 1 mm and the size of the micropores is in the range of 1-100 μm (col. 4, lines 32-36; col. 5, lines 26-28), which overlaps with the claimed ranges. It would have been an obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. in view of Ricci et al. and further in view of Eitenmuller et al. (US 4,610,692).

With respect to claim 31, the modified Lin et al. addresses all the limitations of claim 1, however fails to expressly disclose the implant comprises mixtures of non-coated and polymer-coated granules that are fused together. Eitenmuller et al. discloses an implant for filling bone cavities made of polylactide-coated granules and uncoated granules that are impregnated with a therapeutically-active ingredient (col. 11, lines 18-27; col. 12, lines 7-11). It would have been obvious to one of ordinary skill in

the art to fuse together polymer-coated and non-coated granules in order to create an implant having a rapid-release and sustained-release of biologically active ingredient, as taught by Eitenmuller et al. (col. 7, lines 9-14).

Claims 14-20, 23-25, 28, 30, 32-34 and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 6,869,445) in view of the teachings of Lin et al. and further in view of Ricci et al.

With respect to claims 14-17, Johnson discloses a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, and the granules made of hydroxyapatite and a major portion of the surface area of the granules are coated with polylactic acid and/or polyglycolic acid (col. 2, lines 18-21; col. 5, lines 37-43; col. 6, lines 5-7, 33-42). Johnson also discloses the granules can have a particle size of 1-5mm (col. 6, lines 54-55, and provides an example of the granules having a particle size of 2000 μm (Example 1; col. 8, line 67 – col. 9, line 2). Therefore the particle sizes of Johnson overlaps with the claimed ranges of 350-2000 μm and 500-1000 μm. It would have been obvious to one of ordinary skill in the art to modify the particle size in order to allow for tissue ingrowth while requiring a minimum amount of coating for easy formability and sufficient particle cohesion, as taught by Lin et al. (col. 2, lines 58-64; col. 3, lines 35-39). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Johnson discloses the polymer coating having thickness less than the diameter of the pores of the granules (col. 6, lines 5-13) and the pore size being in the range of 0.3-50 μm (col. 3, lines 52-53), therefore can overlap in the claimed range of 2 μm to 300 μm. However, Johnson fails to expressly disclose that the thickness of the polymer coating in a range of 2 μm to 300 μm corresponds to a weight fraction of about 4% to about 15% of the weight of the implant. Ricci et al. discloses a bioresorbable implant comprising calcium sulfate particles coated with resorbable polymers, wherein the resorbable polymer is made of polylactides or polyglycolides [0025]. Ricci et al. further discloses the polymer coating having a thickness of about 2 μm to about 50 μm and being a range of 0.1% to 50% by weight in order to control the resorption rate of the implant composition [0022], [0026]. It would have been an obvious design modification to one of ordinary to modify the thickness and/or the content of the polymer coating of Johnson in order to give easy formability and provide sufficient particle cohesion and shape retention during the period of tissue ingrowth while attaining the desired resorption rate, as taught by Lin et al. (col. 2, lines 61-64; col. 4, lines 41-46). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 18 and 19, the modified Johnson discloses the granules are spherical (col. 6, lines 54-56).

With respect to claim 20, the modified Johnson fails to expressly disclose the thickness of the polymer being in a range of 5 μm to about 20 μm. Ricci et al. discloses

the polymer coating having a thickness of about 2 μm to about 50 μm which overlaps the claimed range [0022]. It would have been an obvious design modification to one of ordinary to modify the thickness of polymer in order to attain the desired resorption rate of the implant composition, as taught by Ricci et al. [0022]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 23 and 24, the modified Johnson discloses the granules are solid or porous (col. 2, lines 25-26).

With respect to claims 25 and 28, the modified Johnson discloses the porous granules have varying pore diameters, and the pore sizes are preferably in the range of 0.3-50 μm (col. 3, lines 50-52), which overlaps with the claimed ranges of 0-10 μm for micropores and 10-500μm for macropores. It would have been an obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 30, the modified Johnson discloses at least one biological active substance is integrated into the granules and/or into the biocompatible and biodegradable coating, and/or forming a coating layer itself (col. 5, lines 12-14; col. 6, lines 13-14; col. 7, lines 62-66).

With respect to claim 32, the modified Johnson discloses the biodegradable and biocompatible implant is made of two or more kinds of granules, wherein the two or more kinds of granules are made of different biocompatible materials and/or comprising polymer coatings that are distinct from each other and/or having different equivalent diameters (col. 3, lines 18-19, 37-39).

With respect to claim 33, the modified Johnson discloses the granules are solid or porous (col. 2, lines 25-26) and the implant is shaped in a manner to accommodate the granules (col. 7, lines 24 - col. 8, line 4).

With respect to claim 34, the modified Johnson discloses the granules are spherical shaped (col. 3, lines 37-38) and micron-sized (2000 μm) (col. 8, lines 67 – col. 9, line 2) and packed together, and therefore the granules are considered to be mixed with microspheres (mixed with one another) made of a biodegradable and biocompatible material. The modified Johnson also discloses the granules are laoded with at least one biologically active substance (col. 7, lines 62-66).

With respect to claims 38-43, the recitations of “the granules are fused together in a mole in a pressurized $CO_2$ atmosphere under a pressure in a range of about 20 bar to about 200 bar, for at least about 3 seconds” and “the granules are fused together by subjecting them within a mold to a heat treatment at a temperature in a range of about 70° C to about 220° C for at least about 10 seconds” are believed to be process limitations that do not impart any recognizable distinguishing characteristic to the final product.

"Process limitations cannot impart patentability to product claim where product is not patentably distinguished over prior art." In re Dike, 157 USPQ 581 (CCPA 1968). See also MPEP 2113.

It is well-settled that the "[p]resence of process limitations in product claims, which product does not otherwise patentably distinguish over prior art, cannot impart patentability to that product." In re Stephens, 345 F.2d 1020 (CCPA 1965), 145 USPQ 565, citing Dilnot. In any event, the modified Lin et al. discloses the granules fused together in a mold. Thus, the modified Johnson expressly discloses every positively recited structural limitation, and thus meets the limitations recited in the claims, and the product-by-process limitations have not been given significant patentable weight.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of the teachings of Lin et al. and further in view of Ricci et al. and further in view of Bauer et al.

With respect to claims 21 and 22, the modified Jonson addresses all the limitations of claim 14, and further discloses the polymer-linkage is carried out such that after fusing the granules together, the implant material has an open interconnected porosity (col. 3, lines 33-37, 47-51; col. 6, lines 43-45; col. 7, lines 58-62). However, the modified Johnson fails to expressly disclose macropores having an average diameter in the range of about 100-500 μm, or about 200-300 μm. Bauer et al. teaches a bone implant having macropores with sizes in the range of 0.01 – 1 mm (col. 4, lines 32-36; col. 5, lines 26-28), which overlaps with the claimed range. It would have been an

obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only. *In re Aller*, 105 USPQ 233.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of the teachings of Lin et al. and further in view of Ricci et al. and further in view of Glajch et al. (US 6,455,024).

With respect to claims 26 and 27, the modified Johnson addresses all the limitations of claims 14 and 23-25, and further discloses the granules are porous having pores of various diameters, wherein the pore size is preferably in the range of 0.3-50 μm, therefore overlaps with the claimed range. It would have been an obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only. *In re Aller*, 105 USPQ 233. The modified Johnson fails to expressly disclose the inclusion of hollow granules with at least one opening in the wall, wherein the opening in the granule wall is larger than the range of about 0.1-6 μm. Glajq et al. discloses implanting radiotherapeutic agents comprising polymer-coated porous particles having a single pore (hollow particles) ranging in a pore size from about 0.2-500 μm, (col. 3, lines 17-20; col. 4, lines 27-29; col. 7, lines 36-54; col. 8, lines 28-39) used for delivering a gas or liquid or therapeutic (radionuclide) entrapped in the pore. It would have been an

obvious design choice to one of ordinary skill in the art to include hollow granules with an opening in the wall as a means for delivering a therapeutic agent, as desired. With respect to the size of the pore, it would have been an obvious design choice to one of ordinary skill in the art to modify the pore size in order to obtain the desirable therapeutic effects (col. 6, lines 34-37). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only. *In re Aller*, 105 USPQ 233.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of the teachings of Lin et al. and further in view of Ricci et al. and further in view of Glajch et al. and further in view of Bauer et al.

With respect to claim 29, the modified Jonson addresses all the limitations of claims 14, 23 and 26, however fails to expressly disclose the inclusion of macropores having an average diameter in the range of about 200-300 μm. Bauer et al. teaches a bone implant having macropores with sizes in the range of 0.01 – 1 mm (col. 4, lines 32-36; col. 5, lines 26-28), which overlaps with the claimed range. It would have been an obvious design modification to one of ordinary skill in the art to modify the pore sizes in order to optimize bone growth. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only. *In re Aller*, 105 USPQ 233.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of the teachings of Lin et al. and further in view of Ricci et al. and further in view of Eitenmuller et al.

With respect to claim 31, the modified Johnson addresses all the limitations of claim 1, however fails to expressly disclose the implant comprises mixtures of non-coated and polymer-coated granules that are fused together. Eitenmuller et al. discloses an implant for filling bone cavities made of polylactide-coated granules and uncoated granules that are impregnated with a therapeutically-active ingredient (col. 11, lines 18-27; col. 12, lines 7-11). It would have been obvious to one of ordinary skill in the art to fuse together polymer-coated and non-coated granules in order to create an implant having a rapid-release and sustained-release of biologically active ingredient, as taught by Eitenmuller et al. (col. 7, lines 9-14).

Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 6,869,445) in view of the teachings of Lin et al. and further in view of Ricci et al. and further in view of the teachings of Kukla et al. (US 3,918,968).

With respect to claims 35 and 36, the modified Johnson discloses the granules are spray-coated in a fluidized bed machine (col. 5, lines 46-52). It is well known in the art that spray-coating in a fluidized bed machine produces a uniform coating, as demonstrated by Kukla et al. (col. 6, lines 19-23), therefore the thickness attained is considered to be uniform (homogeneous).

With respect to claim 37, the modified Johnson discloses the polymer coating having thickness less than the diameter of the pores of the granules (col. 6, lines 5-13) and the pore size being in the range of 0.3-50 μm (col. 3, lines 52-53), therefore can overlap in the claimed range of 5-20 μm. Ricci et al. discloses it is known in the art to coat a granule with a polymer, wherein the polymer coating has a thickness of about 2 μm to about 50 μm, which overlaps the claimed range [0022]. It would have been an obvious design modification to one of ordinary to modify the thickness of polymer in order to attain the desired resorption rate of the implant composition, as taught by Ricci et al. [0022]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36, 42 and 43 of copending Application No. 10/540323. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 36 and 42 of Application No. 10/540323 recite:

**Biocompatible implant** for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, comprising at least one zone of impermeability to soft tissue and/or epithelial cells in-growth, wherein said implant is comprised of an open porous scaffold and a membrane covering at least a part of said scaffold and being sealed to it such that said scaffold and said membrane form a single piece of matter;

wherein said scaffold is comprised of **fused, biocompatible, biodegradable granules** selected from the group consisting of solid granules, porous granules, hollow granules, hollow granules with at least one opening in the granule, or a mixture thereof; said granules having an equivalent-diameter in a range between about 100 μm to about 2000 μm**, a major portion of said granules being coated with at least one biocompatible and biodegradable layer of a polymer selected from the group consisting of poly(α-hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides,**

**polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof, or blends of those polymers, said polymer coating having a thickness in a range between 1 μm to 300 μm;** and

wherein **said granules having an equivalent-diameter in a range between about 500 μm to about 1000 μm** (*within the range of 350 to 2000 μm*).

The claims of Application No. 10/540323 fail to expressly recite the limitations of the granules being made of biopolymers, bioglasses, bioceramics or a mixture thereof, however it would have been an obvious design choice to one of ordinary skill in the art to modify the type of material for the predictable result of attaining the desired biocompatible property for the implant. Further it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

The claims of Application No. 10/540323 also fails to expressly the weight fraction of the polymer being about 4% to about 15% of the weight of the implant. However, the claim language, as worded, appears to be another way of expressing the thickness, and therefore is considered to be structurally equivalent to the thickness being between 2 μm and 300 μm. Examiner also notes that while the claims of Application No. 10/540323 recite the polymer coating having a thickness in a range between 1 μm to 300 μm instead of 2 μm to 300 μm, the thickness ranges are so similar

that they are considered to be structurally equivalent. However, examiner also notes that where the general conditions of a claim are discloses in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kretschmann et al. (US 5,552,454) discloses an implant material comprising granules of calcium phosphate fused together via a coating of polylactic acid and/or polyglycolic acid.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone/Fax Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615